



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Fischell *et al.*

Serial No.: 10/072,177

Group No.: 1617

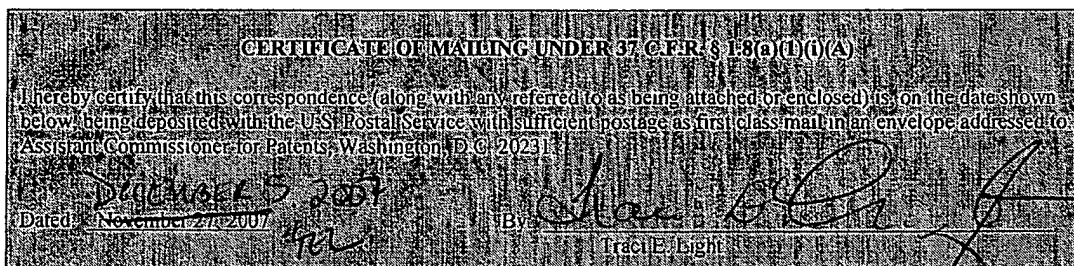
Filed: 02/11/2002

Examiner: Wang, S.

Entitled: **Devices And Methods For Reducing Scar Tissue Formation**

**DECLARATION OF DR. ANDREW PENMAN
UNDER 37 CFR § 1.132**

Mail Stop –Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



Examiner Wang:

I, Dr. Andrew Penman, under penalty of perjury, state that:

1. I am an employee of Angiotech Pharmaceuticals, Inc., owner of the assignee for the pending United States patent application, and hold the title of Vice President, Pre-Clinical Development.
2. I am qualified in the field of treating hyperproliferative tissue response following tissue injury whether induced by disease, accident, or surgery. For more detailed information, I have attached my Curriculum Vitae.
3. I understand that the Examiner has made an assumption that the asserted three references, United States Patent No. 6,726,923 To Iyer et al., United States Patent No. 6,068,654

To Berg et al., and United States Patent No. 3,902,497 To Casey, have compatible technologies. I disagree. I have read and understand both patents and now explain the differences between these three publications.

4. Berg et al. describes a two-piece graft connector described as a tubular band section and a tubular anchor structure. The connector locks in place an end-to-side anastomosis by placing the band section on the side of a first vessel such that it sits on top of the anchor structure place within the second vessel. This configuration allows the band section and the anchor structure to be sutured together such that the first vessel may graft together with the second structure.

5. Iyer et al. describes a one-piece matrix that wraps around a vessel that has been imbibed with an antiproliferative drug.

6. A first difference between Berg et al. and Iyer et al. is that Iyer et al. describes a drug delivery device, while Berg et al. describes a structural support device. Berg et al. does not provide any capability to support drug elution as contemplated by Iyer et al. Further, Iyer's matrix material would likely fail to produce a sufficiently strong graft connector as contemplated by Berg et al.

7. A second difference between Berg et al. and Iyer et al. is that Iyer et al. describes a method to deliver drug after the completion of a surgical procedure, while Berg et al. describes a method to perform a surgical procedure. For example, Berg et al. teaches a method and a device by which an anastomosis may be created. In contrast, Iyer et al. only provides a method and a device by which a drug may be delivered to an anastomosis after it has been formed. After reading Iyer et al., I found no teachings that would be useful in preventing an anastomosis from leaking.

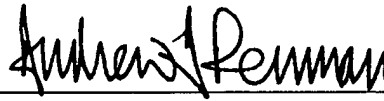
8. In conclusion, I find that Berg et al. and Iyer et al. teach two disparate technologies. Neither publication contains any information so as to suggest that one can be used to improve the characteristics of the other.

9. The third cited reference, a patent issued to Casey, provides a device that is not compatible with either Iyer et al., Berg et al. or the present application by Fischell et al. In particular, Casey teaches a method and a device by which solutions are absorbed into the device.

This is opposite of the desired effects in either Iyer et al. or the present application by Fischell et al. where the device serves as a drug delivery platform. Any sponge device taught within Casey would most likely not function as a drug delivery device.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: November 27, 2007

A handwritten signature in black ink, appearing to read "Andrew Penman", is written over a horizontal line.

Dr. Andrew Penman